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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/014,096	02/04/1993	JAMES S. HUSTON	CRP-008DV(20	9218

7590

11/25/2002

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EXAMINER

ULM, JOHN D

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 11/25/2002

40

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/014,096

Applicant(s)
Huston et al.

Examiner
John Ulm

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 16, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-53, 56-61, and 63-69 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-49, 51-53, 56-61, and 63-68 is/are rejected.
- 7) ☒ Claim(s) 50 and 69 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1646

- 1) Claims 47 to 53, 56 to 61 and 63 to 69 are pending in the instant application. Claim 69 has been added as requested by Applicant in Paper Number 40, filed 16 September of 2002.
- 2) Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's first submission after final filed on 16 September of 2002 has been entered.
- 3) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 5) Claims 50 and 69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 6) Claims 47 to 49, 51 to 53, 56 to 59 and 63 to 68 stand rejected under 35 U.S.C. 102(e) as being anticipated by the Cousens et al. patent (4,741,180) in view of Löfdahl et al. (WO 84/03103, 16 Aug. 1984) and Lehninger (Biochemistry, 1978, Worth Publishing, pages 130-131) for those reasons of record in section 5 of Paper Number 31.

Applicant has again traversed this rejection on the premise that it is in conflict with the decision in *In re Wertheim and Mishkin*, 209 USPQ 554 (CCPA 1981) for those reasons of

Art Unit: 1646

record. Applicant urges that the instant rejection is inconsistent with the procedures described in the M.P.E.P. with respect to the availability of a 102(e) patent reference which is based upon subject matter described in a earlier application of which the patented application is a continuation in part. That portion of the M.P.E.P. concerning this issue is reproduced below.

IV. PARENT'S FILING DATE WHEN REFERENCE IS A CONTINUATION- IN-PART OF THE PARENT

Filing Date of U.S. Parent Application Can Only Be Used as the 35 U.S.C. 102(e) Date If It Supports the Claims of the Issued Child In order to carry back the 35 U.S.C. 102(e) critical date of the U.S. patent reference to the filing date of a parent application, the parent application must (A) have a right of priority to the earlier date under 35 U.S.C. 120 and (B) support the invention claimed as required by 35 U.S.C. 112, first paragraph. "For if a patent could not theoretically have issued the day the application was filed, it is not entitled to be used against another as secret prior art" under 35 U.S.C. 102(e). In re Wertheim, 646 F.2d 527, 537, 209 USPQ 554, 564 (CCPA 1981) (The examiner made a 35 U.S.C. 103 rejection over a U.S. patent to Pfluger. The Pfluger patent (Pfluger IV) was the child of a string of abandoned parent applications (Pfluger I, the first application, Pfluger II and III, both CIPs). Pfluger IV was a continuation of Pfluger III. The court characterized the contents of the applications as follows: Pfluger I - subject matter A, II-AB, III-ABC, IV-ABC. ABC anticipated the claims of the examined application, but the filing date of III was later than the application filing date. So the examiner reached back to "A" in Pfluger I and combined this disclosure with another reference to establish obviousness. The court held that the examiner impermissibly carried over "A" and should have instead determined which of the parent applications contained the subject matter which made Pfluger patentable. Only if B and C were not claimed, or at least not critical to the patentability of Pfluger IV, could the filing date of Pfluger I be used. The court reversed the rejection based on a determination that Pfluger IV was only entitled to the Pfluger III filing date. The added new matter © was critical to the claims of the issued patent.). Note that In re Wertheim modified the holding of In re Lund, 376 F.2d 982, 153 USPQ 625 (CCPA 1967) as to "carrying back" the subject matter to the parent applications. See also Ex parte Gilderdale, 1990 Pat. App. LEXIS 25 (Bd. Pat. App. & Inter. Appeal no. 89-0352) (The examiner made a 35 U.S.C. 102(e)

Art Unit: 1646

rejection over a U.S. patent to Hernandez. Hernandez was a continuation of a continuation-in-part. Both the parent and grandparent had been abandoned. The parent listed a different inventive entity but supported the subject matter of the child's claims. The parent was filed on the same day as the examined application and thus no 35 U.S.C. 102(e) rejection could be made based on the parent's filing date. The Board reversed the rejection, explaining that the Hernandez patent was entitled to the filing date of its parent, as the parent supported the patent claims and 35 U.S.C. 120 was satisfied. Under 35 U.S.C. 120, an application can claim the benefit of an earlier filing date even if not all inventors are the same. However, Hernandez was not entitled to the grandparent filing date because the parent and child applications contained new matter as compared to the grandparent.). Compare *Ex parte Ebata*, 19 USPQ2d 1952 (Bd. Pat. App. & Inter. 1991) (The claims were directed to a method of administering a salt of lysocellin to animals. A 35 U.S.C. 102(e) rejection was made over Martin. Martin was a continuation of an application which was in turn a continuation-in-part of an abandoned application. The grandparent application disclosed administering a manganese complex of lysocellin to animals. The Board found that "the new matter relates to additional forms of lysocellin which are useful in Martin's process, i.e., species or embodiments other than the manganese complex. This is far different from adding limitations which are required or necessary for patentability." Unlike the situation in *In re Wertheim*, Martin's invention as patentable as presented in the grandparent application.). Similarly, when examining PG-PUB applications, in order to carry back the 35 U.S.C. 102(e) critical date of the U.S. patent application publication reference, or those international application publications usable as a reference under 35 U.S.C. 102(e), to the filing date of a parent application, the application must (A) have a right of priority to the earlier date under 35 U.S.C. 120 or 365(c), and (B) support the invention claimed as required by 35 U.S.C. 112, first paragraph.

Because the new matter which was added in the applicant from which the Cousens et al. patent (4,741,180) issued was not needed to support the patentability of the fusion proteins described in the Cousens et al. application (Serial Number 06/717,209), the instant rejection is not in conflict with either the decision in *In re Wertheim* or the guidance provided by the M.P.E.P. Because the new matter added in the subsequent Cousens et al. application was clearly added to support the

Art Unit: 1646

broader claims which subsequently issued therefrom, the instant rejection is supported by the decision in *Ex parte Ebata*, 19 USPQ2d 1952 (Bd. Pat. App. & Inter. 1991) discussed above.

Applicant urges that the two fusion protein of Cousens et al. on which the instant rejection is based do not meet the limitation in the instant claims because the hinge region can not be part of the cleavage site. Applicant is encouraged to review the instant claims. Claim 47 has been carefully reviewed as exemplary of the claimed subject matter and, whereas it requires the presence of a hinge region and a cleavage site in the claimed polypeptide, it does not specify that these two features have to be structurally distinct elements.

Applicant's argument that the linkers employed in the two fusion proteins upon which the instant rejection is based are not inherently flexible completely ignores the Lehninger reference, which has been relied upon for this teaching as explained in the last paragraph beginning on page 7 of Paper Number 31.

7) Claims 60 and 61 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Cousens et al. patent (4,741,180) in view of Löfdahl et al. (WO 84/03103, 16 Aug. 1984) and Lehninger (Biochemistry, 1978, Worth Publishing, pages 130-131). as applied to claims 47 to 49, 51 to 53, 56 to 59 and 63 to 68 above, and further in view of the Cohen et al. patent (4,743,679) for those reasons of record in section 6 of Paper Number 31.

8) Applicant's arguments filed 16 September of 2002 have been fully considered but they are not persuasive.


Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


JOHN ULM
PRIMARY EXAMINER
GROUP 1800